

From this, the Examiner concludes that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the PYY and a PYY agonist, *e.g.*, PYY[3-36], in the method of treating obesity as taught by Malaisse-Lagae *et al.* with a reasonable expectation of success." *Office Action*, Paper No. 10, page 4. Although the Examiner acknowledges that Malaisse-Lagae *et al.* fail to teach the use of PYY or a PYY agonist, or the relative potency of a PYY agonist, the Examiner alleges that one of skill would be motivated to substitute PYY for PP in the method of Malaisse-Lagae because "PP and PYY belong to the pancreatic polypeptide family and both function as inhibitors of pancreatic exocrine as taught by Yoshinaga *et al.* [ ] and by Ueno *et al.*" *Id.* at pages 3-4.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure. *See* M.P.E.P. §§2143.01 and 2143.03.

In a proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. *See In re Chu*, 36 U.S.P.Q.2d 1089, 1094 (Fed. Cir. 1995). The mere fact that references can be modified does not render the resultant modification obvious unless the prior art also suggests the desirability of the modification. M.P.E.P. § 2143.01; *In re Mills*, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990); *see also, In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). This includes what could be characterized as simple changes. *See, e.g., In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

Only when the prior art teaches or suggests the claimed invention does the burden fall on the applicant to rebut that *prima facie* case. *See In re Dillon*, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991). However, a *prima facie* case of

obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.

The rejection of claims 1, 4-12, 23, 29, and 31-33 under 35 U.S.C. § 103(a) is respectfully traversed. First, the cited references, whether taken alone or in combination, fail to teach each and every limitation of the independent claims. Moreover, the Examiner has failed to point out any specific teachings that would lead one of ordinary skill in the art to modify the references to arrive at the present invention with a reasonable expectation of success.

For instance, the references do not disclose or suggest the unexpected ability of PYY and PYY agonists to reduce caloric efficiency. In fact, none of the cited references contemplate the ability of PYY, PYY agonists (or of PP for that matter) to affect caloric efficiency, much less suggest to one of skill in the art an amount of PYY or PYY agonist effective to reduce caloric efficiency. As such, the references fail to disclose or suggest administration of an amount of PYY or PYY agonist effective to reduce caloric efficiency.

Additionally, it is submitted that, based on the cited references, one of skill in the art would not have a reasonable expectation of success in substituting PYY for PP in the method of Malaisse-Lagae *et al.* Although, as pointed out by the Examiner, both PP and PYY have been shown to affect secretion of pancreatic exocrine, there is no suggestion in the cited references that such an effect is necessarily linked to an ability to treat obesity, reduce food intake, or reduce nutrient availability, particularly in view of the known differences in activity of various pancreatic polypeptide family members (as discussed in the response filed October 1, 2002).

For at least these reasons, Applicants submit that the claims are patentable over the prior art of record. As such, withdrawal of this rejection is respectfully requested.

### CONCLUSION

In view of the above, each of the presently pending claims currently under consideration is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass the application to issue. The Examiner is invited to contact the undersigned at (202) 942-6111 with respect to any unresolved issues remaining in this application.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account Number 50-2387, referencing docket number 18528.010.

Respectfully submitted,

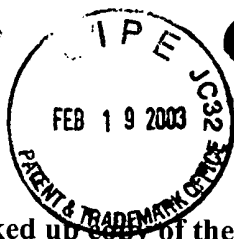


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Marked up copy of the claims:

1. (Amended) A method of treating obesity comprising administering to an obese subject [a therapeutically effective] an amount of a PYY or a PYY agonist effective to reduce caloric efficiency.
6. (Amended) The method of claim 1 wherein about [1  $\mu$ g to about 5 mg] 300  $\mu$ g to about 1 mg of the PYY or PYY agonist is administered per day in single or divided doses.
7. (Amended) The method of claim 1 wherein [about 0.01  $\mu$ g/kg to about 500  $\mu$ g/kg of the PYY or PYY Agonist is administered per dose] a dose of the PYY or PYY agonist sufficient to achieve a peak plasma level equivalent to that achieved by a continuous infusion of PYY or PYY agonist of about 300  $\mu$ g/kg/day to about 1000  $\mu$ g/kg/day is administered.
8. (Amended) A method of reducing food intake comprising administering to a subject [a therapeutically effective] an amount of a PYY or a PYY agonist effective to reduce caloric efficiency.
11. (Amended) The method of claim 8 wherein about [1  $\mu$ g to about 5 mg] 300  $\mu$ g to about 1 mg of the PYY or PYY agonist is administered per day in single or divided doses.
12. (Amended) The method of claim 8 wherein [about 0.01  $\mu$ g/kg to about 500  $\mu$ g/kg of the PYY of PYY agonist is administered per dose] a dose of the PYY or PYY agonist sufficient to achieve a peak plasma level equivalent to that achieved by an infusion of PYY or PYY agonist of about 300  $\mu$ g/kg/day to about 1000  $\mu$ g/kg/day is administered.
23. (Amended) A method for treating conditions or disorders which can be alleviated by reducing nutrient availability in a subject comprising administering to said subject [a therapeutically effective] an amount of a PYY or a PYY agonist effective to reduce caloric efficiency.
31. (Amended) The method of claim 23 wherein about [1  $\mu$ g to about 5 mg] 300  $\mu$ g to about 1 mg of the PYY or PYY agonist is administered per day in single or divided doses.
32. (Amended) The method of claim 23 wherein [about 0.01  $\mu$ g/kg to about 500  $\mu$ g/kg of the PYY of PYY agonist is administered per dose] a dose of the PYY or PYY agonist sufficient to achieve a peak plasma level equivalent to that achieved by a continuous infusion of PYY or PYY agonist of about 300  $\mu$ g/kg/day to about 1000  $\mu$ g/kg/day is administered.